DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 24, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-19

Robert C. Finkbonner, Owner
Finkbonner Shellfish
2301 Lummi View Drive
Bellingham, Washington 98226

WARNING LETTER

Dear Mr. Finkbonner:

On July 19, 1999, the Food and Drug Administration (FDA) conducted an inspection at 2301 Lummi View Drive, Bellingham, Washington. At the conclusion of the inspection, Julie R. Finkbonner, Business Manager, was presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the cooked crabmeat processed by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) due to violations of 21 CFR Part 123.

1. Your firm does not have a HACCP plan for your cooked crabmeat packaged in plastic tubs with snap on lids.

   You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for cooked crab meat to control the hazards of pathogen survival through cooking and pathogen growth through time/temperature abuse.

2. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, you are missing records which indicate the monitoring of your facility's sanitation conditions and practices and any corrective actions you have found it necessary to take.

During the previous inspection, on September 18, 1998, and in a letter from the FDA, dated April 12, 1999, you were notified of the same deficiencies described in points numbered 1 and 2 of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in fifteen months time your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive S.E., Bothell, Washington 98021-4421.

Sincerely,

Bruce W Williamson
for Austin R. Long Ph.D.
Acting District Director

Enclosures:
Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
WSDA